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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,083	12/28/2001	Richard A. Terwilliger	WORLD-01000US1 SRM	3945
23910	7590	10/03/2003	EXAMINER	
FLIESLER DUBB MEYER & LOVEJOY, LLP FOUR EMBARCADERO CENTER SUITE 400 SAN FRANCISCO, CA 94111			LACYK, JOHN P	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,083

Applicant(s)

TERWILLIGER ET AL.

Examiner

John P Lacyk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25,28,49-54,65-71,73-76 and 92-124 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25,28,49-54,65-71,73-76 and 92-124 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10-11
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-25, 28, 49-54, 65-71, 73-76, 92-99, 101-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox in view of Candelaria et al.

Lennox teaches a method and device for delivery of therapeutic agents in conjunction with isotope seed placement. Lennox teaches a device for brachytherapy where the radioactive seeds (22) and spacers (24) are held in a continuous elongate member (See Figure 2). Lennox teaches that Pd-103, Au-198, I-125 and Ir 192 are used in brachytherapy (col. 1, lines 20-25) and that a short half-life and low energy is desired (col. 1, lines 33-34). The spacers can contain a therapeutic hormone or drug, and that an outer layer can be biodegradable to allow release of a therapeutic drug or hormone (col. 4, lines 33-40).

Lennox fails to teach that the seed contains the drug or hormone and is bio-absorbable. However, it would have been obvious to one of ordinary skill in the art to put the therapeutic agent of the spacer in the seed, as this would involve a simple combination of claimed elements. It has been held obvious to one having ordinary skill in the art at the time the invention was made to put the drug or hormone in the seed, since it has been held that integrating into one piece articles which have formerly been separate involves only routine skill in the art. Further, the seeds would have to be bio-absorbable to release the drug or hormone, as the spacers are.

Lennox also does not teach making the solid member thick enough to deter normal tissue necrosis. However, Lennox teaches that normal tissue necrosis is

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undesirable (col. 1, lines 29-33) and making the wall of the catheter or other radiation delivery device thicker to provide some shielding is notoriously well known in the art, and would have been obvious to one of ordinary skill at the time of the invention.

Although Lennox teaches that the device should be made of a bio-absorbable polymer, but does not name the polymer (col. 3, lines 29-32), the exact number of days over which the bio-absorbable or bio-degradable elements will degrade, the use of an echogenic material, the durometer range, steam sterilizability, or the use of air bubbles. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device of Lennox of any known bio-absorbable polymer or to make it echogenic or give it air bubbles or any other desirable characteristic, since it has been held to within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Lennox fails to teach that the device is axially stiff but radially flexible. Candelaria teaches a radiotherapy source ribbon having variable radiotherapy. There are seeds that are spaced as needed and held in a solid, elongate member that is flexible enough to pass through a tortuous passage but axially stiff enough to push through said passages (col. 5, lines 35-38). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the radially flexible and axially stiff ribbon of Candelaria with the radiation therapy device of Lennox, as this would allow the device to pass through tortuous passages without jamming or collapsing as explained above.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 123-124 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 123 and 124 appear to be directed to steps in a method of manufacturing the device and not to structural limitations of the device itself.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 93-100, 102-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Horowitz.

Horowitz discloses a therapeutic element (See Figures 5-6) that uses a polymer that is a bio-absorbable material to “encapsulate and connect” a plurality of radioactive seed elements.

7. Claims 101, 104-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horowitz in view of Lennox and Candelaria for the same reasons as discussed above.

8. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., not using spacers and axially rigid and radially flexible) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that both Lennox and Candelaria use spacers and that applicant's device uses a polymeric material to encapsulate and position the seeds and that without the use of spacers the prior art would have no mechanism to provide the positioning of the seeds in the desired intervals. Since the claims use the open-ended "comprising" there is nothing preventing the prior art from having seeds in that the claim is not limited to not having them. Also there is no claim language in the claims to provide support for such an argument. There is no language directed to any kind of mechanism to provide positioning the seeds in a desired interval and there is no language claimed to using a polymeric material to encapsulate and position the seeds, as one example only, claim 1 recites only that the seed elements are dispersed within the elongate solid member, there is no language directed to any of the arguments stated above and therefore the rejection is still deemed to properly read on the claimed language. Applicant also argues the Candelaria is different from applicant's claimed invention in that the elongate member of applicant's device is "sufficiently rigid to allow expulsion of the

member while maintaining the spacing between seeds and be flexible and pliable enough to move with the tissue as the tissue shrinks back to pre-operative size". Again there is no claim language to support such an argument, all that is claimed is that it is axially rigid and radially flexible, which is clearly taught by the prior art. There is no claim language directed to allowing expulsion of the member while maintaining the spacing between seeds or that it move with the tissue as the tissue shrinks. Further since the prior art clearly shows the member being both specifically axially rigid and radially flexible it appears that the functions would have been inherently performed by the material of Candelaria. Since the material is radially flexible it would inherently move when the tissue shrinks.

With respect to the additional novel features those have been addressed in the rejection.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P Lacyk whose telephone number is 703-308-2995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0858.



John P Lacyk
Primary Examiner
Art Unit 3736

J.P. Lacyk
August 11, 2003